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CENTRAL FAX CENTER App. No. 10/828,765

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REMARKS

This is a full and timely response to the outstanding Office Action mailed November 27, 2007. Reconsideration of the application and allowance of presently pending claims as amended, are respectfully requested.

A. Present Status of Patent Application

Applicant has amended claims 20 and 24. New claim 31 has been added. Claims 20-31 remain pending in the present application. Support for the amendments to claims 20 and 24 is found at least at paragraphs 0010, 0026 and 0043 of the Specification. Support for new claim 31 is found at least at paragraph 0011 of the Specification.

Drawings

Applicant notes that the drawings filed 20 April 2004 have been accepted.

B. Response to Action**1. Claim Rejections Under 35 USC 103(a) over Bird**

Claims 20, 29 and 30 were rejected as allegedly unpatentable under 35 USC 103 (a) over Bird US 6581600. It was contended that Bird teaches a pressure circuit and a respiratory circuit. Applicant respectfully disagrees. The system of Bird is that a **closed circuit**, comprising an inspiratory limb (tube 78), and expiratory limb (tube 88) both of which are coupled at one end to a ventilator (916), and at the other end to a junction device, or mixer (59). See Bird column 5, lines 46-62. The patient is connected via an appropriate patient interface, e.g. endotracheal tube or cannula at outlet 68. Air thus runs, at a relatively constant pressure and flow, from the inspiratory port 17 of the ventilator, through the tubing 78, into the mixer 59, and thence to the patient's lungs. Return gases from the patient exit the lungs, enter the mixer 59, thence to the expiratory tube 88 and back to the expiratory port 18 of the ventilator. This defines a **single closed circuit**. The fact that a nebulizer 56 is fluidically coupled to the mixer 59 by a

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tube 123 (and by body 111) does not alter the fact that there is a single-pressure closed circuit. The tube 123 only serves to permit the nebulizer to be positioned remotely; it **does not constitute a separate pressure circuit**. This remote nebulizer placement of Bird emphasizes the distinction by applicant's claimed invention over the art, since Bird thereby teaches away from one aspect of applicant's invention, that is, the placement of the nebulizer near to the patient (proximal to the airway). This latter feature is now more specifically claimed in amended claims 20 and 24. Bird thus teaches away from applicant's claimed invention, and as such the rejection thereover should be withdrawn.

2. Claim Rejections Under 35 USC 103(a) over Bird in view of Davidson

Claims 21-28 were rejected as allegedly unpatentable under 35 USC 103 (a) over Bird US 6581600 in view of Davidson, GB 2272389.

With respect to the rejection of these claims, based in whole or in part upon Bird, the same comments applied with respect to the rejection of claims 20, 29 and 30 are similarly applicable here. In view of Bird's teach away effect related at least to nebulizer placement, it is inappropriate to combine Bird with any other reference.

Moreover, Davidson merely describes a vibrating mesh-type nebulizer, and does not teach, suggest or disclose a method of respiratory therapy. In particular, Davidson does not teach, suggest or disclose a method of respiratory therapy comprising at least the steps of providing a pressure-assisted breathing system having a pressure-generating circuit and a respiratory circuit adapted to be coupled to a patient interface device, wherein the pressure-generating circuit contains a first gas flow of sufficiently high-volume to maintain positive pressure in the system and wherein the respiratory circuit contains a second gas flow of lower volume than the first gas flow, as claimed by applicant. Davidson is limited to describing a **self-contained aerosolization apparatus, which has utility alone for inhalation therapy**. For these reasons, Davidson does not, and can not teach ventilator respiratory circuits, nor a pressure-generating circuit and a respiratory circuit, nor specific nebulizer placement therein.

Thus, neither reference individually, or combined, teaches applicant's claimed invention wherein an aerosolized medicament is introduced into a pressure-assisted breathing system at a location outside the high-volume flow of gas in the pressure-generating circuit. This step avoids the dilution of the aerosolized medicament by the high-volume gas flow in the pressure-generating circuit and results in an increased amount of aerosolized medicament delivered to the patient.

Even assuming, *arguendo*, that it would have been obvious to combine the teachings of Bird and Davidson as proposed by the Examiner, such combination does not result in the invention of amended claims 21-28 because the combination fails, at least, to include the step of introducing the aerosolized medicament into the system at a location outside the high-volume gas flow of the pressure-generating circuit of the system, and in close proximity to the patient, thereby avoiding the dilution of the aerosolized medicament and increasing the amount of aerosolized medicament delivered to the patient's respiratory system.

As recited above, Bird discloses a closed circuit system, comprising an inspiratory limb and expiratory limb, both of which are coupled at one end to a ventilator, and at the other end to a junction device, or mixer. Davison merely discloses a stand-alone nebulizer apparatus. However, neither Bird nor Davison teach or suggest the step of introducing aerosolized medicament into a location outside the high-volume gas flow in the pressure-generating circuit, such as the respiratory circuit, thereby avoiding dilution of the aerosolized medicament and increasing the amount of aerosolized medicament delivered to the patient's respiratory system.

In *Takeda Chemical Industries v. Alphapharm*, No 2006-1329 (Fed. Cir. 2007), the Federal Circuit Court affirmed the District Court's finding of nonobviousness of a compound claim. The District Court found that the patentee's (*Takeda*) claim was nonobvious both because there was no motivation in the prior art references to select the compound that was patented, and because the prior art taught away from the use of such compound. The Federal Circuit affirmed, noting that the *Graham* analysis remains applicable post *KSR*, and that at least

in cases involving new chemical entities, it remains necessary to identify some reason that would have led a chemist to modify a known compound

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in a particular manner to establish *prima facie* obviousness of the claimed compound.

Takeda at page 10.

With specific reference to teaching away, the Court stated that "any suggestion to select compound b [the NCE] was essentially negated by the disclosure of the Sodha II reference".

Takeda at page 13.

For at least the reason that Bird teaches a remote nebulizer placement, the Takeda analysis precludes a finding that Bird, or Bird combined with Davison, can render applicant's claims *prima facie* obvious.

Unobviousness of applicant's claimed invention is further exemplified by claims 23 and 26-28 which point out the unexpectedly high (compared to the prior art) delivery efficiencies realized from the practice of one or more embodiments of the practice of applicant's invention. As set forth in these claims and described in the specification (e.g. paragraphs 0040 - 0043), considerably more of the aerosolized medicament, such as surfactant may delivered to the patient using the method of the invention. Thus only about 4 ml of liquid is required to provide a therapeutic dose to a 1 kg infant. These unexpected results are further evidence of the unobviousness of the present invention.

With further regard to the dependent claims, as the independent claims are allowable over the prior art of record, then their dependent claims are allowable as a matter of law, because these dependent claims contain all features/elements/steps of their respective independent claim. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

Additionally and notwithstanding the foregoing reasons for the allowability of independent claims 20 and 24, the dependent claims recite further features/steps and/or combinations of features/steps (as is apparent by examination of the claims themselves) that are patentably distinct from the prior art of record. Hence, there are other reasons why these dependent claims are allowable.

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Conclusion

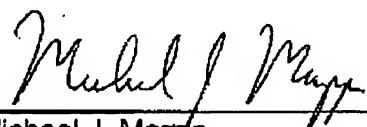
In view of the foregoing, Applicants submit that pending claims 20-31 satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all rejections is respectfully requested and a prompt mailing of a Notice of Allowance is solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at 650.283.6790.

Respectfully submitted,
Nektar Therapeutics

Date: 2/27/08

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